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4417 LANCASTER PIKE
WILMINGTON, DE 19805

EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/846,589

Applicant(s)

FAMODU ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44-50 and 52-56 is/are allowed.
- 6) ☒ Claim(s) 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. In response to the previous Office action, a written restriction requirement (Paper No. 7, mailed on September 24, 2002), Applicants filed an amendment and election received on December 2, 2002 (Paper No. 9). Said amendment cancelled Claims 31-43 and added new Claims 44-56. Thus, Claims 44-56 are pending in the instant Office action and will be examined herein.

Priority

2. The instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 09/352,990 filed on July 14, 1999 now USPN 6,255,090 as requested in the transmittal sheet.

3. The instant application is not granted the benefit of priority for the U.S. Provisional Application No. 60/092,866 filed on July 15, 1998 as requested in the declaration and the first line of the specification because the instant application does not comply with the rules set out in 35 U.S.C. § 119 (e): namely, no common inventors are found between the instant application and the provisional application. Applicants are requested to withdraw claims to priority benefits. The priority date granted for purposes of prior art in this Office action is the filing date of the instant application that is July 15, 1998.

Information Disclosure Statement

4. The information disclosure statement (IDS) filed on June 18, 2001 (Paper No. 2) fails to fully comply with 37 C.F.R. § 1.98(a)(2). The references not considered lack a publication date; their citation is incomplete without said date. All other documents in said Information Disclosure statement were considered as noted by the Examiner initials in the copy attached hereto. Applicants should file a supplemental IDS containing complete citations of the crossed-out references.

Objections to the Specification

5. The specification is objected to for lacking continuity data in the first paragraph. As noted above, the instant application cannot claim the benefit of U.S. Provisional Application No. 60/092,866. Moreover, the claim of benefit for U.S. non-Provisional Application no. 09/352,990 now USPN 6,255,090 filed on July 14, 1999 is missing. Appropriate amendment to the specification is required (see M.P.E.P. § 201.11).

6. The specification is objected to because the title is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. § 606.01). The Examiner suggests the following new title:

---Polynucleotides encoding Cysteinyl tRNA Synthetase from *Zea Mays*---

7. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its

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completeness is essential. The Examiner suggests the inclusion of the full name of the enzymes disclosed, aspartyl, cysteinyl, tryptophanyl, and tyrosyl tRNA synthetases, and the source species, *Zea mays*, *Oryza sativa*, *Triticum aestivum* and *Glycine max*, for completeness.

8. The specification is objected to for now containing an inappropriate amendment. In an amendment filed on December 2, 2002 (Paper No. 9), Applicants amended page 9 when page 6 should have been amended. With the amendment having been entered, Applicants must correctly amend page 6 and return page 9 to its originally filed form.

Claim Objections

9. Claim 51 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The 30 nucleotides required of Claim 51 would not represent at least 80% sequence identity to a sequence encoding SEQ ID NO:10 as required by parent Claim 44. The Examiner suggests rewriting Claim 51 as an independent claim.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 51 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is wholly unclear if Claim 51 is a polynucleotide fragment of the polynucleotide

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of Claim 44 by the claim language "wherein the ...sequence...is comprised by"? If the function required in Claim 44 is also required in Claim 51? Clarification is required. The claim will be examined as if it is not limited by the limitations in Claim 44.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 51 is rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 51 is drawn to nucleic acid molecules comprising polynucleotides encoding fragments of SEQ ID NO:10 in the absence of functional language.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could

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predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification discloses a polynucleotide encoding the cysteinyl tRNA synthetase and fragments thereof. Applicants have fully described the genus relating to said SEQ ID NO with both sequence limitations and functional limitations (i.e., having cysteinyl tRNA synthetase activity). The limited size of the fragment renders it highly unlikely that such a fragment will maintain the activity claimed. The genus of the instant claims also contains polynucleotides within the sequence fragment limitations, but having different function. Applicants have not fully described a genus that has sequence fragment limitations in the absence of functional limitations.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claim 51 is rejected under 35 U.S.C. § 102(e) as being anticipated by Lalgudi *et al.*

(USPAP US 2002/0013958). The instant claim is drawn to a polynucleotide containing at least 30 nucleotides of SEQ ID NO:9.

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Lalgudi *et al.* teach numerous polynucleotides from corn, one of which is SEQ ID NO:1857 which is a 249 base pair sequence matching SEQ ID NO:9 1631-1879 (see attached alignment). The Examiner notes that Lalgudi *et al.* disclose SEQ ID NO:1857 as early as the priority document 60/085,331 filed on May 12, 1998.

Closest Prior Art and Examiner's Comments

13. The closest prior art identified by the Examiner is GenBank Accession Number AB009048, *Arabidopsis thaliana* genomic DNA, chromosome 5 (published December 2, 1997). This GenBank Accession Number teaches a 71,736 bp DNA sequence a portion of which having limited (<50%) similarity to a sequence encoding SEQ ID NO:10 (see attached alignment). This art is clearly not within the scope of Claims 44-50 and 52-56.

14. In addition to noting the above closest prior art, the Examiner is noting the following for clarity and completeness of the record. The instant claims are drawn to a polynucleotide that encodes a cysteinyl tRNA synthetase (Cys-tRS) and that is structurally related to SEQ ID NOs:9 (DNA) and/or 10 (amino acid). From *Zea mays* (corn), SEQ ID NO:10 is a 599 amino acid sequence, and SEQ ID NO:9 exactly encodes said sequence with 2085 base pairs. This sequence does *not* start with a methionine (or the less common valine) and does *not* end with a stop codon. The specification describes SEQ ID NO:10 as a cysteinyl-tRNA synthetase by virtue of limited homology (40-45%) with putative Cys-tRS's from *H. influenzae* and *E. coli* (see Example 4).

Cys-tRS's in the art range in size from 489-750 amino acids in length, thus, SEQ ID NO:10 is within the art-defined range of enzymes. A putative Cys-tRS from *A. thaliana* is only about 40% identical to that of *H. influenzae* and *E. coli*, as similarly described for the *Zea mays*

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sequence in the instant specification. From these data, the putative assignment of Cys-tRS functionality for SEQ ID NO:10 is reasonable and fulfills the utility requirement.

Other plant Cys-tRS sequences in the instant application have low homology to a sequence encoding SEQ ID NO:10; *Oryza sativa* at 76% and *Glycine max* at 47% (see attached alignments). Such plant sequences would be expected to have a higher homology to the *Zea mays* sequence (see Peeters *et al.*). Moreover, in GenBank Accession Number AY104190, a slightly longer DNA sequence is disclosed by DuPont's maize mapping group that is 2120 base pairs long encompassing SEQ ID NO:9 exactly end-to-end (see attached alignment); in this case, DuPont does **NOT** identify the sequence as a Cys-tRS. It is noted that in AAD07974 just 5' of the SEQ ID NO:9 corresponding base pairs is a "tga" stop codon and just 3' of SEQ ID NO:9 is a "tga" stop codon. Thus, it would seem that SEQ ID NO:9 is not a part of the full length open reading frame. However, none of the above data taken alone or together are sufficient to form a *prima facie* case to discount the putative functional assignment of SEQ ID NO:10 by Applicants in the instant specification. Thus, the claims have utility and adequate written description.

Other Art of Relevance

15. The following references are noted to complete the record:

- a) Peeters *et al.* Duplication and Quadruplication of *Arabidopsis thaliana* Cysteinyl- and Asparaginyl-tRNA Synthetase Genes of Organellar Origin. *Journal of Molecular Evolution* (2000) 50:413-423.

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Conclusion

16. Claims 44-50 and 52-56 are allowed in the Office action; Claim 51 is not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

February 20, 2003

